

AD\_\_\_\_\_

Award Number: W81XWH-11-1-0772

TITLE: Translational Pharmacologic Efficacy Studies of Glial Growth Factor 2 (GGF2) in Spinal Cord Injury Models and in the Veterinary Clinical Setting

PRINCIPAL INVESTIGATOR: Dr. Natasha Olby

CONTRACTING ORGANIZATION: North Carolina State University  
Raleigh, NC 27607

REPORT DATE: October 2012

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. <b>PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.</b>					
1. REPORT DATE 16 October 2012		2. REPORT TYPE Annual		3. DATES COVERED 30 September 2011 – 29 September 2012	
4. TITLE AND SUBTITLE Translational Pharmacologic Efficacy Studies of Glial Growth Factor 2 (GGF2) in Spinal Cord Injury Models and the Veterinary Clinical Setting				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-11-1-0772	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr. Natasha Olby  E-Mail:				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) North Carolina State University, Raleigh, NC 27695-7003				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT  The purpose of the multi-institutional translational project is to identify the most appropriate dosing schedule and route of administration of glial growth factor 2 (GGF2) in the treatment of rodent spinal cord injury and then to translate this work to dogs with naturally occurring spinal cord injury. The tolerability and pharmacokinetics of GGF2 in dogs will be determined using the dosing regimen identified in the first phase of the work, and then the efficacy of GGF2 will be determined in dogs with intervertebral disc herniations causing acute onset of paralysis. According to the schedule of work, the initial 18 months of research are being performed at the other institutions involved in this multi-institutional project. Work is scheduled to start at North Carolina State University (NCSU) in 2013 and we have completed an IACUC proposal that is approved at the NCSU level and has been submitted to the DOD for review in readiness to start this work.					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			USAMRMC
			UU	3	19b. TELEPHONE NUMBER (include area code)

## Table of Contents

	<u>Page</u>
Introduction.....	1
Body.....	1
Key Research Accomplishments.....	1
Reportable Outcomes.....	1
Conclusion.....	1
References.....	1
Appendices.....	""%

**Introduction**

The objectives of this multi-institutional translational project are to determine the most appropriate route and dosing regimen for GGF2 in the treatment of acute spinal cord injury in rodents, to test the tolerability and the pharmacokinetics of GGF2 in dogs using the data established in the first phase of the work and then to test this dosing regimen for efficacy in a naturally occurring model of canine spinal cord injury.

**Body**

The canine work, to take place at North Carolina State University, is to begin 18 months after the start of the grant once the dosing data is available and we have therefore not yet completed any research at NCSU. In readiness for starting the tolerability and pharmacokinetic work early in 2013, we have been briefed on the progress of research performed by Dr. Jean Wrathall at Georgetown Medical Center, and have completed an IACUC proposal that has been approved by NCSU and that is currently being reviewed by the Department of Defense. We have also purchased the digital video equipment necessary to videotape dogs to collect data on outcome during the canine clinical trial work.

**Key Research Accomplishments**

Not applicable

**Reportable Outcomes**

Not applicable

**Conclusion**

Not applicable

**References**

Not applicable

**Appendices**

Not applicable